4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1534]

Sun Pharmaceutical Industries, Ltd.; Withdrawal of Approval of Three Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of three abbreviated new drug applications (ANDAs) held by Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc. (Sun Pharmaceutical). These drug products are no longer marketed, and Sun Pharmaceutical has requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993-0002, 240-402-7945, Trang.Tran@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Sun Pharmaceutical has informed FDA that these drug products are no longer marketed and requested that FDA withdraw approval of the applications. Sun Pharmaceutical has also waived its opportunity for a hearing and requested withdrawal of approval under a Consent Decree of Permanent Injunction (Decree) entered in *United States* v. *Ranbaxy Laboratories, Ltd. et al.*, JFM 12-250 (D. Md.) on January 26, 2012. The Decree

specifies that Sun Pharmaceutical must never submit another application to FDA for these withdrawn drugs and must never transfer these ANDAs to a third party.

Application No.	Drug	Applicant
ANDA 065174	Clarithromycin Tablets USP, 250 milligrams (mg) and 500 mg	Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540
ANDA 065382	Clarithromycin for Oral Suspension USP, 125 mg/5 milliliters (mL) and 250 mg/5 mL	Do.
ANDA 075747	Ciprofloxacin Tablets USP, Equivalent to (EQ) 250 mg base, EQ 500 mg base, and EQ 750 mg base	Do.

Therefore, approval of the applications listed in the above table, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)).

Dated: May 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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